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13 *Bard Peripheral Vascular, Inc.*

14  
15 **IN THE UNITED STATES DISTRICT COURT**  
16  
**FOR THE DISTRICT OF ARIZONA**

17 IN RE: Bard IVC Filters Products Liability  
18 Litigation

19 No. 2:15-MD-02641-DGC

20  
21 **DEFENDANTS C. R. BARD, INC.**  
22 **AND BARD PERIPHERAL**  
23 **VASCULAR, INC.'S MOTION AND**  
24 **INCORPORATED MEMORANDUM**  
25 **TO EXCLUDE THE OPINIONS OF**  
26 **DAVID GARCIA, M.D. AND**  
27 **MICHAEL STREIFF, M.D. AND**  
28 **MEMORANDUM OF LAW IN**  
28 **SUPPORT**

29 (Assigned to the Honorable David G.  
30 Campbell)

31 **(Oral Argument Requested)**

## **MOTION**

2 Pursuant to Federal Rule of Evidence 702, and *Daubert v. Merrell Dow*  
3 *Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Defendants C. R. Bard, Inc. and Bard  
4 Peripheral Vascular, Inc. (collectively “Bard”) respectfully move this Court to exclude  
5 certain opinions of Plaintiffs’ expert witnesses, David Garcia, M.D. and Michael Streiff,  
6 M.D.

## **MEMORANDUM OF POINTS AND AUTHORITIES**

## I. BACKGROUND

9 The plaintiffs' hematology experts, Dr. David Garcia, and Dr. Michael Streiff  
10 (collectively the "Doctors"), offer three categories of opinions that should be excluded.  
11 First, the Doctors submitted an addendum to their report which merely regurgitates  
12 Dr. Kessler's findings. They have no expertise in any of the topics in Dr. Kessler's  
13 voluminous report, and did no independent analysis of Dr. Kessler's conclusions. Second,  
14 the Doctors opine on physician expectations and what Bard should have, and failed to,  
15 disclose to physicians. *See Report*, attached as Exhibit A (the "Report"), at pp. 6-7.  
16 However, the Doctors do not have any expertise in implanting or removing IVC filters,  
17 developing warning labels, or corporate conduct or ethics, and testified that they largely  
18 based these opinions on Dr. Kessler's report. And, these opinions should be excluded  
19 because the only relevant inquiry is whether the physician who implanted the filter in each  
20 specific plaintiff was adequately warned. Lastly, Dr. Garcia's case-specific opinions for  
21 Plaintiff Doris Jones should be excluded in their entirety because they lack reliable  
22 methodology. *See Jones Report*, attached as Exhibit B. Accordingly, Bard moves to  
23 exclude these opinions under Rule 702 and the standards set forth in *Daubert* and its  
24 progeny.

## II. ARGUMENT AND CITATION OF AUTHORITY

## A. “Opinions” Regurgitating Dr. Kessler’s Report Should Be Excluded.

27 As Judge Posner explained in *Dura Automotive Systems of Indiana, Inc. v. CTS*  
28 *Corp.*, 285 F.3d 609 (7th Cir. 2002):

[t]he Daubert test must be applied with due regard for the specialization of modern science. A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty. That would not be responsible science. A theoretical economist, however able, would not be allowed to testify to the findings of an econometric study conducted by another economist if he lacked expertise in econometrics and the study raised questions that only an econometrician could answer. If it were apparent that the study was not cut and dried, the author would have to testify; he could not hide behind the theoretician.

*Id.* at 614. *See also Turner v. Burlington N. Santa Fe R. Co.*, 338 F.3d 1058, 1062 (9th Cir. 2003) (affirming the exclusion of an expert's testimony because he "intended to use [a second expert's findings] as substantive evidence of his ultimate conclusions," because the second expert's findings were not the "type reasonably relied on by experts in the particular field" and the "probative value of this otherwise inadmissible evidence d[id] not outweigh its prejudicial effect").

Here, the Doctors provide an addendum to their expert report paraphrasing Dr. Kessler's report. (*See* Ex. A, Rep., at pp. 8-9.) The Doctors claim that their review of Dr. Kessler's report (and Dr. Betensky's analysis contained in Dr. Kessler's report) somehow corroborates or bolsters their own medical opinions. However, aside from merely repeating Dr. Kessler's conclusions and providing an avenue for duplicative testimony, the Doctors fall well short of all Rule 702 and *Daubert* requirements. Dr. Streiff spent less than five hours reviewing Dr. Kessler's 270-page, 707-paragraph report, and 448 pages of schedules. (July 17, 2017, Deposition of Dr. Michael Streiff ("Streiff Dep."), attached as Exhibit C, at 295:13-17.) Dr. Garcia spent about 25 to 30 hours total working on this litigation, although he could not estimate specifically what portion of that was spent with Dr. Kessler's materials. (June 21, 2017, Deposition of Dr. David Garcia ("Garcia Dep."), attached as Exhibit D, at 33:9-22.) When asked if he read Dr. Kessler's report in its entirety, Dr. Garcia could only respond "[a]t some level, I've read it in its entirety...I would say there were some pages I read much less closely than others, but I've looked at the text of every page in some form or fashion." (Ex. D, Garcia Dep. 204:-20.) The Doctors never spoke with Dr. Kessler. (Ex. C, Streiff Dep. 302:10-12; Ex. D, Garcia Dep. 209:24-25.) And they did not contribute to, change,

1 or modify any of Dr. Kessler's findings. (Ex. D, Garcia Dep. at 210:7-15.) The Doctors do  
2 not "say anything in [their] addendum about Dr. Kessler's findings that he himself doesn't  
3 say in his own report." (Ex. D, Garcia Dep. at 211:3-6.) Dr. Garcia agreed that "in drafting  
4 [the] addendum and kind of essentially regurgitating what Dr. Kessler found in his report,  
5 [the Doctors] attempt[ed] to be as accurate as possible in describing Dr. Kessler's  
6 findings." (Ex. D, Garcia Dep. 210:1-5.) Dr. Streiff agreed that they did not attempt to  
7 modify Dr. Kessler's finding in any way, testified that "[w]e read through the report and  
8 kind of pulled these right [] out of his report," and described their incorporation of  
9 Dr. Kessler's report as merely "a summary of what we read in the, in his, his report." (Ex.  
10 C, Streiff Dep. 302:15 – 304:5.)

11 Moreover, the Doctors admittedly lack the expertise to opine on the same material  
12 contained in Dr. Kessler's report, and do not rely on litigation-driven expert reports, or  
13 even the underlying corporate documents, in their medical practice. The Doctors are not  
14 experts in designing, engineering, testing, manufacturing, or marketing IVC filters, and  
15 are not experts in corporate ethics, FDA compliance, post-market surveillance, or  
16 reviewing internal medical device company documents (which they have never reviewed  
17 before this litigation). (Ex. C, Streiff Dep. 98:13 – 101:24; Ex. D, Garcia Dep. 83:16 –  
18 85:12.) Dr. Garcia further explained that "I relied on Dr. Kessler's assessment of a very  
19 large body of information that I'm not, you know, familiar with or – or used to looking at  
20 and considered him – him and his conclusions to be reliable. And that – that's the basis of  
21 what I've written here." (Ex. D, Garcia Dep. 207:20 – 208:8.) The Doctors did not  
22 independently verify Dr. Kessler's methodology or review or assess any of the underlying  
23 documents or data. (Ex. C, Streiff Dep. 283:7 – 284:4; 307:6-24; 307:25 – 308:11; Ex. D,  
24 Garcia Dep. 212:8 – 213:6.) As a result, all opinions the Doctors offer based on  
25 Dr. Kessler's report should be excluded.

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**B. The Court Should Exclude Opinions On Physician Expectations and Corporate Conduct.**

First, the opinions contained in the Doctors’ “Physician Expectations” section of their report should be excluded because they are also based on Dr. Kessler’s report. (See Ex. A, Rep. at pp. 6-7 (opining that “in order for physicians to make reasonable risk-benefit assessments regarding filters, it is critically important that manufacturers of IVC filters continuously apprise the clinicians who order and implant IVC filters about their safety profile, performance characteristics, design problems, and internal risk assessments,” and that “Bard’s complete transparency about the safety profile of its IVC filters is paramount”); Ex. C, Streiff Dep. 274:23 – 277:5 (testifying that “by the time we got to [the “Physician Expectations” section], we had seen the Kessler report, and we added that in there. So I think that’s, that came, it came from I guess both David [Garcia] and I’s reviewing of the Kessler report...And then we went on further to make...an addendum on, that goes into, more in detail about that report, or at least several points from it”); Ex. D, Garcia Dep. 192:22 – 194:10; 196:11 – 198:11; 201:4 – 202:25 (testifying that statements in this section were based on Dr. Kessler’s report).) Moreover, the Doctors provide no explanation of how Dr. Kessler’s conclusions, which purport to be regulatory in nature, relate to their medical opinions. Dr. Garcia testified that he simply agreed with Dr. Kessler’s and Dr. Betensky’s analysis, and that “I guess one way you could say is that, assuming their analysis is true, it just strengthens the conclusions of my report” because “the information stated in this addendum only further highlights the risks of IVC filters, beyond what I could have done using publicly available peer reviewed information that’s cited in my report.” (Ex. D, Garcia Dep. 217:12-25.)

24       Second, the Doctors are not qualified to opine on what is required of manufacturers  
25 to warn physicians who implant IVC filters. The Doctors do not have any expertise in  
26 implanting or removing IVC filters, developing warning labels, or corporate conduct or  
27 ethics, and testified that they largely based these opinions on their brief review of  
28 Dr. Kessler's report. The Doctors have never placed or removed an IVC filter. (Ex. C,

1 Streiff Dep. 97:25 – 98:2; Ex. D, Garcia Dep. 52:24 – 53:2.) Dr. Garcia admitted that he  
 2 does not make the ultimate decision of whether a patient should receive a filter, but is  
 3 sometimes part of the decision-making process with other physicians. (Ex. D, Garcia  
 4 Dep. 54:7-18.) He does not have any role in deciding what brand filter to place. (Ex. D,  
 5 Garcia Dep. 56:8-16.) Similarly, Dr. Streiff makes recommendations in consultation with  
 6 other physicians, does not place filters himself, and stated “I defer to my colleagues in  
 7 [interventional radiology] what, you know, what filter they use...whether they use  
 8 permanents or an optional filter.” (Ex. C, Streiff Dep. 133:22 – 134:20.) And, the Doctors  
 9 have no experience developing device labeling or warnings that would otherwise allow  
 10 them to opine on what physicians should expect regarding the risks or warnings of IVC  
 11 filters. (Ex. C, Streiff Dep. 101:23 – 102:9; Ex. D, Garcia Dep. 86:5-12.)

12 Finally, the Doctors’ personal speculation on what physicians expect regarding  
 13 IVC filters is irrelevant and does not fit the facts of this case. The only relevant inquiry for  
 14 the plaintiffs’ failure to warn claim is whether their implanting physicians were  
 15 adequately warned under their respective jurisdictions’ laws. *Cloud v. Pfizer, Inc.*, 198 F.  
 16 Supp. 2d 1118, 1130 (D. Ariz. 2001) (“The trial court ‘must ensure that the proposed  
 17 expert testimony is relevant to the task at hand,...i.e., that it logically advances a material  
 18 aspect of the proposing party’s case.’”) (*quoting Daubert v. Merrell Dow Pharms., Inc.*,  
 19 43 F.3d 1311, 1317 (9th Cir.1995)).

20 **C. Dr. Garcia Did Not Use Reliable Methodology or Analysis for Jones-  
 21 Specific Opinions.**

22 Plaintiff Jones has a fractured strut retained in her right pulmonary artery.  
 23 Dr. Garcia opines that “the presence of a foreign body in a pulmonary artery branch  
 24 represents a permanent, significant risk factor for the development of in situ thrombosis.”  
 25 (Ex. B, Jones Rep. at p. 1.) Dr. Garcia did not review any imaging, and admitted that he is  
 26 not qualified to do so. (Ex. D, Garcia Dep. 220:6-18.) He reviewed certain medical  
 27 records, but did not know which ones and the plaintiffs have never produced a list of those  
 28 records to Bard. (*Id.* at 10:12-23.) He only relied on one specific article for his opinions,

1 and “the evidence that an IVC filter can induce the risk of thrombosis and a general  
2 knowledge that other published literature suggest that to be the case.” (Ex. D, Garcia  
3 Dep. 221:18-2.) However, Dr. Garcia could not point to a single piece of literature or  
4 other scientific evidence to support his extrapolation from entire filters causing  
5 thrombosis to filter fragments in a different part of the body causing thrombosis. (*Id.* at  
6 225:24 – 228:14.) Dr. Garcia could not quantify any increased risk that Plaintiff Jones is  
7 exposed to for thrombosis because of the strut (*Id.* at 242:9-17), could not state with a  
8 reasonable degree of medical certainty that Plaintiff Jones will develop thrombus from  
9 any injury to her vessel wall from the filter strut (*Id.* at 245:12-19), and could not state  
10 with a reasonable degree of medical certainty that if Plaintiff Jones developed pulmonary  
11 embolism in the future, that it would be related to the strut as opposed to other causes,  
12 such as those that caused her pulmonary embolism prior to receiving the filter (*Id.* at  
13 246:17 – 248:17). Moreover, even though Dr. Garcia stated in his report that “Mrs. Jones  
14 should be therapeutically anticoagulated indefinitely” (Ex. B, Jones Rep. p. 2), he testified  
15 that he could not actually make that statement because Plaintiff Jones may be  
16 contraindicated to anticoagulation, and that he did not know one way or the other. (Ex. D,  
17 Garcia Dep. 222:14 – 223:21; 249:14 – 250:16.) Indeed, at the end of his deposition,  
18 Dr. Garcia asked “if you would permit it, I’d like to learn more about – after today – about  
19 why she had thrombosis in the first place, because that could impact my opinion about  
20 whether she – whether her need for anticoagulation is specific to the filter fragment  
21 versus, you know, related to something else.” (*Id.* at 254:6-13.) Because Dr. Garcia could  
22 offer no support for his opinions by either medical literature or differential diagnosis, all  
23 of his case-specific opinions for Plaintiff Jones should be excluded.

### 24 **III. CONCLUSION**

25 The Doctors’ opinions based on their brief review of Dr. Kessler’s report, including  
26 their opinions regarding physician expectations, are not only inadmissible under Rule 702,  
27 but are also unhelpful and unreliable under *Daubert*. And, Dr. Garcia’s opinions in  
28

1 Plaintiff Jones' case lack any scientific support or methodology. Accordingly, these  
2 opinions should be excluded in their entirety.

3 DATED this 24th day of August, 2017.

4 s/Richard B. North, Jr.

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2 **CERTIFICATE OF SERVICE**  
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6 I hereby certify that August 24, 2017, the foregoing was electronically filed with  
7 the Clerk of Court using the CM/ECF system which will automatically send e-mail  
8 notification of such filing to all attorneys of record.  
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